DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-163/S-057

Mallinckrodt Inc
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Attention: Marianne Robb
Official Correspondent

Dear Ms. Robb:

Please refer to your supplemental new drug application dated June 30, 2004, received July 2, 2004, submitted under section 505(b)/ of the Federal Food, Drug, and Cosmetic Act for Restoril (temazepam) Capsules.

We acknowledge receipt of your submission dated September 9, 2004.

This supplemental new drug application provides for an additional strength of 22.5 mg.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter with the minor editorial revision listed below.

Correct the following typographical error in the HOW SUPPLIED section.

22.5mg
Opaque blue capsules, with the opaque blue body imprinted “FOR SLEEP” on one side and M on the other side in red, and ~~a~~ an opaque blue cap imprinted “RESTORIL 22.5 mg” twice in red.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted June 30, 2004, immediate container and carton labels submitted June 30, 2004). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-163/S-057.” Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Sara Stradley, Regulatory Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Director
Division of Anesthetic, Critical Care and
Addiction Drug Products
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport

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